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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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08/31/2001

Robert V. Hageman

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05/27/2009

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EXAMINER

LOCKARD, JON MCCLELLAND

ART UNIT

PAPER NUMBER

1647

MAIL DATE

DELIVERY MODE

05/27/2009

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

| | | | |
|------------------------------|--------------------------------------|---------------------------------------|--|
| Office Action Summary | Application No. 09/944,930 | Applicant(s) HAGEMAN ET AL. | |
| | Examiner JON M. LOCKARD | Art Unit 1647 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 06 March 2009.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-22 is/are pending in the application.
- 4a) Of the above claim(s) 15-22 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-14 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 24 January 2002 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>1/24/02, 5/8/03</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Election/Restrictions

1. Applicant's election without traverse of Group I, claims 1-14, in the reply filed on 06 March 2009 is acknowledged. Claim 15-22 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on 06 March 2009.

Status of Application, Amendments and/or Claims

2. The response filed 06 March 2009 has been entered in full. Claims 15-22 have been withdrawn as discussed above. Therefore, claims 1-22 are pending, and claims 1-14 are the subject of this Office action.

Information Disclosure Statement

3. The information disclosure statements (IDS) submitted on 24 January 2002 and 08 May 2003 have been considered by the examiner.

Specification

4. The disclosure is objected to because of the following informalities: it contains embedded hyperlinks and/or other form of browser-executable code. See for example, page 16, line 29. Applicant is required to delete the embedded hyperlinks and/or other form of browser-executable code. See MPEP § 608.01.

Claim Rejections - 35 USC § 102

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

6. Claims 1-13 are rejected under 35 U.S.C. 102(b) as being anticipated by Adami et al. (U.S. Pat. No. 5,714,458, issued 03 February 1998; cited by Applicant).

7. Adami et al. teach stabilized pharmaceutical compositions comprising basic fibroblast growth factor (i.e., FGF-2), cysteine, and a reducing agent, including dithiothreitol (DTT), a thiol derivative (See column 2, lines 4-48). Adami et al. also teach liquid and lyophilized formulations of said composition (See column 3, lines 33-43), and when reconstituted has a pH between 5.0 and 7.0 (See column 4, lines 24-27). While Adami et al. is silent with regard to the FGF lacking any disulfide bonds or the composition having a hemolytic potential of less than about 10%, it is noted that a compound and all of its properties are inseparable; they are one and the same thing (see *In re Papesch*, CCPA 137 USPQ 43; *In re Swinehart and Sfiligoj*, 169 USPQ 226 (CCPA 1971)). Moreover, the exact values for the concentrations of the various components of the composition are part of routine optimization in the art, as noted at pg 5, line 21 to pg 6, line 2 of the instant application. Therefore, the Adami et al. reference meets all the limitations of claims 1-3.

Art Unit: 1647

Claim Rejections - 35 USC § 103

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

9. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

10. Claims 4 and 5 are rejected under 35 U.S.C. 103(a) as being unpatentable over Adami et al. as applied to claims 1-13 above, and further in view of Flaa et al. (U.S. Pat. No. 6,165,981, filed 07 March 1995).

11. The teachings of Adami et al. are summarized above. Adami et al. does teach the use of n-acetyl-cysteine as a reducing agent. However, n-acetyl-cysteine and DTT were known to be useful reducing agents in pharmaceutical compositions as taught by Flaa et al. (See column 5, lines 27-30). It would have been obvious to a person of ordinary skill in the art at the time the invention was made to use n-acetyl-cysteine as taught by Flaa et al. in the stabilized pharmaceutical composition comprising FGF as taught by Adami et al. One of ordinary skill in

Art Unit: 1647

the art at the time the invention was made to make this modification since n-acetyl-cysteine and DTT were known to be useful reducing agents in pharmaceutical compositions, and Flaa et al. disclose that DTT is effective in protecting the FGF protein in solution against oxidation. The expectation of success is high since n-acetyl-cysteine and DTT were both known to be useful reducing agents in pharmaceutical compositions as taught by Flaa et al. (See column 5, lines 27-30). It is noted that the exact values for the concentrations of the various components of the composition are part of routine optimization in the art, as noted at pg 5, line 21 to pg 6, line 2 of the instant application.

12. Thus, the claimed invention as a whole was *prima facie* obvious over the combined teachings of the prior art.

Summary

13. No claim is allowed.

Art Unit: 1647

Advisory Information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to **Jon M. Lockard, Ph.D.** whose telephone number is **(571) 272-2717**. The examiner can normally be reached on Monday through Friday, 8:00 AM to 4:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, **Manjunath N. Rao, Ph.D.**, can be reached on **(571) 272-0939**. The fax number for the organization where this application or proceeding is assigned is **571-273-8300**.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Jon M. Lockard, Ph.D.
May 26, 2009

/Jon M Lockard/
Examiner, Art Unit 1647